

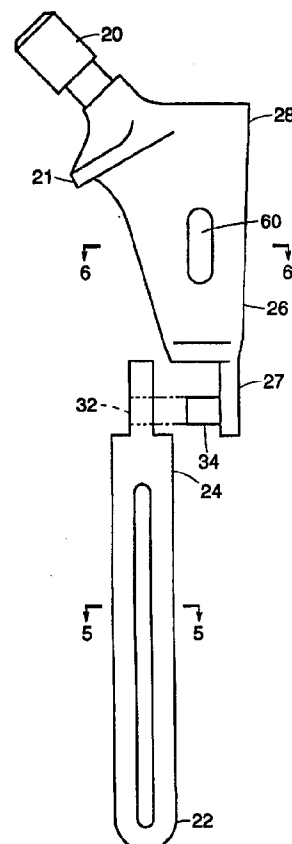


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(54) Title: MODULAR FEMORAL TRIAL HIP REPLACEMENT SYSTEM**(57) Abstract**

A multipiece trial femoral component kit (16) for use in sizing a femoral cavity prior to implantation of a prosthetic femoral implant. The trial femoral component kit (16) has at least two distal trial components (12', 12'') of different size and two proximal trial components (14', 14'') of different size and mating elements (34', 36') which allow the proximal and distal components to be releasably coupled to form a femoral trial prosthesis (10). The distal trial component combines with the proximal trial component to form the stem of the femoral trial prosthesis, the joint of the two components located in the circumferential area (54) between the gluteal tuberosity (46) and about 2" below the pectineal line (48) of the femur (40) when the femoral trial is inserted within the femur (40). The distal and proximal components may further include means for selectively combining the proximal and distal components to form a femoral trial prosthesis that corresponds to an available prosthetic femoral implant. The dimensions of the distal and proximal components may be undersized when compared to the corresponding regions of the prosthetic femoral implant.



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5 MODULAR FEMORAL TRIAL HIP REPLACEMENT SYSTEM
 BACKGROUND OF THE INVENTION

1. Field of the Invention

 This invention relates to an orthopedic trial femoral component for use in determining the correct prosthetic femoral component for implantation from a group of
10 prosthetic femoral components. More particularly, this invention relates to a two-piece trial component to be used as a guide for the surgeon in selecting the proper sized prosthetic femoral component.

2. Description of the Prior Art

 Orthopedic surgery to replace a femur head and neck with a prosthetic
15 component or to replace a previously implanted femoral prosthetic device is a complex operation requiring a relatively lengthy surgery. There has been a need to shorten and simplify this procedure while simultaneously providing the best fit between the prepared femoral canal and the prosthetic implant. This is especially true since many of the patients requiring such surgery are elderly or multi-trauma patients who require a series
20 of operations and the longer the patient is under anesthesia, the greater the risk.

 To determine the appropriate femoral implant size, the surgeon takes and examines X-rays of the femur. He then uses a trial component as a guide in preparing the femur to receive the chosen prosthesis. The surgeon attempts to select a trial implant which fits so that his final implant will likewise fit.

25 In the past, surgeons have used a series of one-piece trial prostheses which were identical in size to corresponding prosthetic implants. These prosthetic femoral implants came in discrete sizes which had been determined to cover the widest range of patients that surgeons were likely to encounter.

 The surgeon would prepare the femoral canal by rasping and/or reaming and
30 through guesswork, he would determine if the one-piece femoral trial prosthesis fit. Difficulties were encountered with a one-piece femoral trial prosthesis because the proximal body of the trial prosthesis blocked the view of the medullary canal and this made it difficult to determine the correct one-piece prosthesis. The surgeon, upon implementation, often found that either his preparation of the femur was incorrect or the
35 geometry of the prepared femur did not allow for the preliminarily chosen femoral implant to be used. Often it was extremely difficult to discern whether the problem or

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obstruction was located distally around the stem or proximally around the body portion of the trial prosthesis.

Manufacturers compensated for these difficulties by providing a series of femoral prosthetic implants with identical stem lengths but different neck/body sizes or vice versa. The surgeon also was provided with a series of one-piece trial prostheses with multiple stem and body sizes. The surgeon then used trial and error methods to determine the best fitting trial prosthesis from the different trial prostheses.

To overcome this position, modular two-piece trial prostheses were developed such as disclosed in United States Patent No. 5,100,407. The disclosed modular trial system provides a two-piece trial component kit with a plurality of interchangeable heads and stems. This two-piece trial prosthesis separates the head and neck region of the trial prosthesis from the stem portion to provide the surgeon with a cross-sectional view of the bone where the surgeon cuts the femur. With this two-piece trial system, the stem and proximal body components of the femoral trial prosthesis are fitted separately so that the surgeon can address each fit independently and more easily.

The two-piece trial prosthesis of U.S. Patent No. 5,100,407 is particularly adapted for resection cases where the surgeon must remove the head and neck of the femur in order to replace it with a femoral implant. The surgeon prepares a bone bed for the proximal body component of the two-piece trial prosthesis by using the trial proximal component as a guide for the necessary proximal cut of the femur and/or to check the accuracy of his rough cut.

The surgeon then moves onto fitting the distal trial stem component by first inserting various trial stem sizes to see which fits the patient best. The surgeon can quickly access the stem fit because there is no proximal head and body to block his view so he can clearly see the stem within the femoral canal. In the one-piece system, it would not be possible to view the distal fit because the integral head/body would obstruct the surgeon's view.

In the described two-piece trial system, the trial prosthesis is composed of a stem component and a body component, thus the distal and proximal fit of the stem within the femoral canal is addressed by use of a single trial component. Therefore, it is not always possible to size the stem of the prosthesis both distally and proximally within the femoral canal. In revision cases, where a previous femoral implant is being replaced and the epiphysis of the femur is gone, it becomes increasingly important to

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fit the femoral canal with the implant along its entire length. Thus, there has been a need in the art for a trial prosthesis which adequately address the aforementioned difficulties and drawbacks of existing devices.

SUMMARY OF THE INVENTION

5 It is an object of the present invention to provide a two-piece trial femoral prosthesis to be used as a guide in determining the correct prosthetic femoral implant for implantation into a femur from a group of prosthetic femoral implants.

It is also an object of the present invention to provide a two-piece trial femoral prosthesis that allows the proximal and distal fit of the femoral canal to be accurately and
10 independently performed.

It is a further object of the present invention to provide a two-piece femoral trial prosthesis that addresses proximal and distal fill of the femoral canal of the femur with different components so that the surgeon can select the correct prosthetic femoral implant for implantation into the femur from a group of prosthetic femoral implants.

15 It is an object of the invention to provide a two-piece femoral trial prosthesis that separates the stem of the trial prosthesis into two separate components so that maximum interference between the implant along the length of the femoral canal can be achieved.

It is an object of the invention to provide a method of addressing both proximal
20 and distal fill of the femoral canal by the use of combinable proximal and distal trial components having an area of intersection when inserted into the femur that corresponds to the metaphysis.

These and other objects are provided by the present invention which includes a multi-piece trial femoral component kit for use in sizing a femoral cavity prior to
25 implantation of a prosthetic femoral implant. The trial component kit includes a number of different distal components and a number of different proximal components which are combinable to form numerous different-sized femoral trial prostheses. The distal and proximal trial components are coupled to produce a trial femoral prosthesis which can be used as a guide for correctly sizing the cavity within the femur for a prosthetic
30 femoral implant.

Each distal portion and proximal component includes a mating element to couple the two pieces together. The combination of the distal trial component and proximal trial component together form the stem of a modular trial femoral prosthesis.

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The two components of the modular trial prosthesis couple in the stem of the trial prosthesis corresponding to the circumferential area on the femur between the gluteal tuberosity and about two (2) inches below the pectineal line, i.e., between the soft spongy bone of the epiphysis and the hard cortical bone of the metaphysis. The mating elements are configured so that the two-piece trial femoral prosthesis can be held together to form a one-piece unit but can be selectively separated so that more than one proximal component can be coupled to each distal component or vice versa.

The present invention uses a variety of proximal stem geometries that are independent of the various distal stem geometries. With this unique separation of the stem of the trial prosthesis, and the various distal and proximal stem geometries available, proximal and distal fit of the femoral canal can be evaluated independently, i.e., the distal stem portion separate from the proximal stem portion, so that an implant can be selected that captures maximum interference along the length of the femoral canal.

Each mating element can be provided with a key or keyway shaped to allow selected proximal components to be coupled to selected distal components to ensure that the surgeon can only form a two-piece trial prosthesis which corresponds to an actual prosthetic femoral implant.

The femoral trial prosthesis may be undersized so that minimal resistance of the trial within the prepared femur will ensure a proper fit of the femoral implant. The distal trial component may have a diameter that is approximately .75 mm smaller than the corresponding portion of the actual implant while the proximal trial component may have a diameter that is approximately 1.0 mm smaller than the diameter of the corresponding portion of the actual implant.

These and other objects and advantages of the present invention will become apparent from the following description of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Similar reference characters in the drawings denote similar elements through the views:

FIG. 1 is an elevational view of a two-piece modular femoral trial prosthesis of the present invention;

FIG. 2 is an elevational view of an uncoupled two-piece modular femoral trial prosthesis of the present invention;

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FIG. 3 is an illustration of a modular trial component kit of the present invention;

FIG. 4 is the dorsal view of the right femur;

FIG. 5 is a cross-sectional view of the distal femoral component of FIG. 2 taken along line 5-5;

5 FIG. 6 is a cross-sectional view of the proximal femoral component of FIG. 2 taken along line 6-6;

FIG. 7 is a cross-section of a resected femur receiving the distal component of the trial prosthesis of the present invention coupled to the trial positioner handle;

FIG. 8 is a cross-section of a resected femur with the distal component of a trial
10 prosthesis of the present invention being retrieved by a retrieval hook;

FIG. 9 is a cross-section of the proximal component of a trial prosthesis and a distal end of a trial positioner handle of the present invention; and

FIG. 10 is a cross-section of a resected femur with the proximal component of the trial prosthesis of the present invention coupled to the trial positioner handle.

15 DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 and 2, there is shown the two-piece trial femoral prosthesis of the present invention generally denoted as 10. Trial femoral prosthesis 10 is composed of a distal trial component 12 coupled to a proximal trial component 14. Distal trial component 12 has a distal portion 22 that is received in the prepared femoral
20 canal 140 (see FIG. 8) and a proximal portion 24 that couples with the distal portion 26 of the proximal trial component 14. A proximal portion 28 of the proximal trial component 14 includes a flange or collar 21 that butts against and rests on the bone where the surgeon resected the femur, a trunion 20 which is used to mount a spherical ball (not shown) and an opening 30 (shown in FIG. 7) to receive a trial positioner
25 handle 25.

The trial femoral prosthesis 10 represents the combination of a distal trial component 12 and a proximal trial component 14 which may be formed from a multipiece trial femoral component kit 16. Referring to FIG. 3, the multipiece trial femoral component kit 16 may include, for example, a number of different distal trial
30 components 12', 12'', 12''' and a number of different proximal trial components 14', 14''. These can be combined to form numerous different-sized femoral trial prostheses 10.

The distal trial components may vary, for example, in diameter, length and geometry. FIG. 5 shows a cross-section 112 of distal component 12 with a diameter

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23. It being understood that the cross-sectional shape shown in FIG. 5 is representative and that various cross-sectional shapes are possible. The distal trial components, for instance, may vary from 12.5 mm to 21.5 mm in 1.5 mm diameter increments, may be 180 mm or 250 mm in length and may be bowed or straight in configuration. The bowed distal trial components can be assembled to create a right or left trial prosthesis. Referring to FIG. 3, there is illustrated distal trial component 12', 12" which are both straight and of the same length but vary in diameter. Distal trial component 12''' is bowed and is longer than either distal components 12' or 12".

The proximal trial components 14', 14" vary proximally in neck length of the femur, collar width as well as proximal calcar area geometry. The neck length of the femur is varied by changing the length of the trunion 20 while the collar width refers to changes in the size of the lip created by collar 21. The proximal calcar area refers to the proximal stem 19 on proximal component 14 which begins at a location just below the collar 21 and extends to the distal end 27 of the proximal component 14. The proximal calcar area of the different proximal components 14 vary in cross-sectional area and length.

FIG. 6 shows a cross-section 114 of proximal component 14 with a diameter 25. It is to be understood that the term diameter as used herein is used to refer to the width of both circular and non-circular cross-sections of distal and proximal components 12, 14 and is illustrated in FIGS. 5 and 6 as 23, and 25, 25'. It again being understood that the cross-sectional area shown in FIG. 6 is for illustrative purposes and that various cross-sectional shapes of the proximal stem 19 are possible.

The length of the proximal components 14 are varied with the proximal calcar geometry so that the proximal components 14 extend to roughly the same area when inserted within the prepared femoral canal 140. In this manner, a proximal component 14 with a larger cross-sectional size at a point just distal to the collar 21 will have a longer length so that the distal end 27 of the proximal component 14 will extend deep enough into the patient's prepared femoral canal 140. Representative lengths of the proximal stem 19 are approximately 40-50 mm. Multiple other variations in proximal component 14 will be apparent to persons of ordinary skill in the art.

The contents of a preferred trial kit of the present invention include eighteen (18) total pieces with seven (7) straight distal trial components of 180 mm in length, seven (7) bowed distal trial components of 250 mm in length and three (3) proximal trial

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components. These eighteen (18) components allow the surgeon to construct forty-two (42) combinations of monolithical femoral implants. The distal trial components 12 vary from about 12.5 mm to about 21.5 mm in diameter, preferably in about 1.5 mm increments. Proximally the trial components 14 vary in neck length of the femur, collar width as well as proximal calcar area geometry. Of course, these combinations can be multiplied by adding different distal and/or proximal trial components.

When the trial femoral prosthesis 10 of the present invention is fitted within the femur, the joint 32 between the distal and proximal trial components 12, 14 is located in the metaphysis 52 of the femur 40 (see FIG. 4) or more specifically the circumferential area 54 between the gluteal tuberosity 46 and about two inches (2") below the pectineal line 48. The area of intersection is the area between the soft spongy bone of the epiphysis 50 and the hard cortical bone of the metaphysis 52 or an area approximately half-way into the metaphysis 52 of the femur.

The combination of the distal trial component 12 with the proximal trial component 14 together form the stem 18 of the trial femoral prosthesis 10. In other words, the stem 18 of the trial femoral prosthesis 10 is composed of two separate pieces. In particular, the stem 18 of the trial prosthesis 10 is formed by the combination of the proximal stem 19 of the proximal trial component 14 with the distal trial component 12. In this manner, the stem 18 of the trial prosthesis 10 which is inserted into the femoral canal of the femur 40 can be independently and separately sized both distally and proximally by the distal and proximal trial femoral components 12, 14.

By having different-sized and geometrically-shaped distal and proximal trial components 12, 14 available, and by independently selecting different proximal and distal components 12, 14 to form the stem 18 of the trial prosthesis 10, the surgeon can choose the best size monolithical femoral implant that will maximize distal-to-proximal interference of the medullary canal. The ability to maximize the fit of the stem of the femoral implant within the femoral canal is particularly important in revision surgical procedures where a previous femoral implant is to be replaced and the epiphysis 50 of the femur 40 has been removed.

The femoral trial prosthesis 10 may be undersized when compared to the prosthetic femoral implant so that minimal resistance upon fitting the trial prosthesis 10 will ensure that the femoral implant will make contact with the bone. Accordingly, the cross-sections of the distal and the proximal trial components 12, 14 in the trial kit 16

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must be undersized when compared to the respective distal and proximal regions of the implant to which the distal and trial components correspond. The distal trial component 12 may have a diameter 23 that is approximately .5 to 1.25 mm, and preferably .75 mm, smaller than the corresponding diameter of the implant and the proximal trial component 14 may have a diameter 25 that is approximately .5 to 1.25 mm, and preferably 1.0 mm, smaller than the corresponding diameter of the actual femoral implant. It is to be understood that the distal and proximal components 12, 14 can be undersized by varying amounts, i.e., .5 to 1.25 mm, along their respective lengths.

At distal end 27 of proximal trial component 14 is a male element 34 which is adapted to be inserted within a corresponding opening 36 (not shown) in the proximal end 24 of distal femoral component 12. The male element 34 and opening 36 are preferably a square-drive socket combination and preferably of 3/8" size, although other socket configurations are equally useful. In the square drive combination, as shown in FIG. 7, the male element 34 is provided with a spring 38 and detent ball 39 designed to selectively, releasably and repeatably couple distal trial component 12 to proximal trial component 14. The ball 39 is depressed as male element 34 is slid within corresponding opening 36 and then springs out, locking the components together, upon reaching a predetermined point. The spring 38 is sized so that a predetermined amount of hand pressure tending to separate proximal trial component 14 from distal trial component 12 depresses the ball 39 and allows the two-piece trial prosthesis to be uncoupled. It is understood that the respective male element 34 and opening 36 may be reversed or any other coupling mechanism may be utilized that allows the distal trial component 12 and proximal trial component 14 to be selectively, releasably, and repeatably connected.

Because implant manufacturers only supply a discrete number of femoral implants, it is necessary to ensure that the surgeon only chooses a proximal and distal component 12, 14 that couple to form a trial prosthesis 10 that corresponds to an actual implantable prosthesis.

In order to achieve this, the male element 34 or opening 36 may be provided with a key or keyway (not shown) sized to allow selected distal components 12 to be coupled to selected proximal components 14 so that only a two-piece trial prosthesis 10 can be formed that corresponds to an available femoral implant. A different way of

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performing this same function is to provide a label 60 on the proximal trial component 14 which provides a list of the different distal components 12 that will couple with that proximal trial component 14 to form a trial prosthesis 10 which corresponds to an available femoral implant. Using the label method requires the surgeon to check that
5 the combination of distal and proximal components 12, 14 used correspond to an available femoral implant.

The process of utilizing the trial component kit 16 of the present invention will now be described. Initially, the surgeon is supplied with a series of proximal trial components 14', 14", etc., from the kit 16, one corresponding in size to each size
10 stem/body portion of an implantable prosthesis. Likewise, the surgeon is supplied with a group of distal trial components 12', 12", 12"', etc., from the kit 16, one corresponding in size to each distal stem portion provided on an implantable prosthesis. With the modular trials of the present invention, the surgeon can begin the procedure with attention to either proximal or distal fit.

15 In the case of revision surgery, the failed femoral prosthesis and cement should first be removed. Thereafter, and in the case of resecting the femur, the surgeon then prepares for the osteotomy. The appropriate broach is laid against the femur at the point where the medial aspect of the broach lies slightly distal to the most distal medial bone loss. The osteotomy can be marked off the broach with methylene blue. The
20 surgeon makes the osteotomy in line with the angle of the broach. The broach can be used as a cutting surface.

In most revision cases, the surgeon can very clearly access the distal femoral canal. If, however, the technique used to implant the previous femoral component did not open the medial aspect of the greater trochanter 42 (see FIG. 4), the surgeon
25 should precede distal reaming by opening this area of the proximal bone. The surgeon should have straight-line access to the distal femoral canal.

The surgeon can now prepare the distal femoral canal for the distal trial component 12. The femoral canal should be enlarged by reaming to accept one of the available distal stem components 12. Reaming should extend into the femoral canal
30 to a point distal to the full length of the anticipated implant. It is expected that in most cases involving the 250 mm length stem and in some cases involving the 180 mm length version, the distal canal will require at least about 1 mm of over-reaming.

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At any time during the reaming process, the surgeon may insert the distal trial component 12 into the reamed canal to check the implant's ultimate fit. For these purposes trial handle positioner 25 is provided, which releasably attaches to the distal stem trial component 12. Referring to FIG. 5, a male mating element 134 which has the same configuration as male element 34 of proximal trial component 14 attaches to the distal trial component 12 in the same manner as mating element 34 of the proximal trial component 14.

The distal stem trial component 12 is undersized, preferably by approximately .75 mm in diameter as compared to the corresponding portion of the actual implant. Therefore, the distal trial component 12 trial should seat in the canal without much resistance. A distal trial component 12 that does encounter resistance indicates a tight fit of the implant within the femoral canal.

Referring to FIG. 6, a retrieval hook 70 is provided to retrieve the distal stem trial component 12 and pull it out of the femur 40 in the unlikely event that the distal trial component 12 slips down the femoral canal. When distal stem preparation is complete, the surgeon can focus on proximal bone preparation.

The proximal region of the revision femur usually experiences far more unpredictable bone loss than does the distal canal. Therefore, before beginning proximal bone preparation, the proximal trial component 14 is inserted in order to access the potential fit of the trial. The same trial handle positioner 25 that is used with the distal stem component 12 is used with the proximal trial component 14. Trial handle positioner 25 fits within opening 30 in order to couple with proximal trial component 14. Mating element 134 of the trial handle positioner 25 couples with the proximal component 14 in opening 30 in the same manner as mating element 34 couples with opening 36 in the distal trial component 12.

Regardless of whether or not the modular proximal trial component 14 is used before proximal bone preparation, both midshaft reamers and broaches should be used to prepare the proximal area of the femur 40. Seating of proximal trial component 14 should be attempted periodically throughout bone preparation. The proximal trial component 14 is undersized approximately 1.0 mm compared to the dimensions in the corresponding region of the implant. The proximal trial component 14 therefore should offer little resistance.

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The surgeon who has completed distal stem preparation should ensure that the chosen proximal trial component 14 couples with the distal trial component 12 already reamed and fitted to form a trial femoral prosthesis 10 that corresponds to an available implant and vice versa for the surgeon who prepares the proximal portion of the femur first.

The modular trial components 12, 14 can be assembled to perform the final trial reduction. The surgeon places the trial prosthesis 10 in the femur 40 and if the trial prosthesis 10 seats with minimum resistance, the corresponding implant will make proper contact with the bone upon implantation. The trial handle positioner 25 can be inserted into the proximal trial component 14 to make manipulation of the trial prosthesis 10 easier. If the modular trial components 12, 14 were used during bone preparation, it is unlikely that any difficulties will occur while inserting the trial prosthesis 10. If any resistance is experienced as the trial prosthesis 10 is inserted, the surgeon should redo the broaching and reaming steps of the bone preparation. Plastic heads are placed on the trunion 20 to complete the trial reduction. The surgeon may even desire to take intraoperative X-rays to judge the fit and alignment of the trial prosthesis. The modular trial prosthesis 10 is removed upon verifying the fit and the corresponding one-piece implant is implanted within the femur using known techniques.

While the present invention has been described in its essentials, and by illustrative examples, those skilled in the art can appreciate that many changes and modifications may be made without departing from the spirit and scope of the present invention.

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WE CLAIM:

1. A two-piece femoral trial prosthesis (10) having a stem to be inserted into the femoral canal for use in sizing a femoral canal prior to implantation of a selected prosthetic femoral implant, comprising:
 - 5 a distal trial component (12) having a distal end (22) and a proximal end (24);
 - a proximal trial component (14) having a distal end (26), a collar (21) and a proximal end (28), wherein said proximal end of said distal trial component is repeatably connectable to said distal end of said proximal component; and
 - wherein the portion of the proximal component (14) distal to the collar (21)
 - 10 together with the distal component (12) combines to form the stem of said trial femoral prosthesis which is inserted into the femoral canal (140), wherein said distal and proximal components are sized such that the connection between the distal and proximal components is located within the metaphysis (52) of the femur in the circumferential area (54) between the gluteal tuberosity (46) and about 2" below the
 - 15 pectineal line when the femoral trial prosthesis is inserted within the femoral canal.
2. The femoral trial prosthesis (10) of claim 1 wherein the dimensions of the distal and proximal components (12, 14) are undersized by different amounts when compared to the dimensions of the corresponding regions of prosthetic femoral implant.
- 20 3. The femoral trial prosthesis (10) of claim 2 wherein the dimensions of the distal component (12) are undersized by varying amounts along its length when compared to the dimensions of the corresponding regions of the prosthetic femoral implant.
4. The femoral trial prosthesis (10) of claim 2 wherein the dimensions of the
- 25 stem portion of the proximal component (14) are undersized by varying amounts along the length when compared to the dimensions of the corresponding regions of the prosthetic femoral implant.
5. A multi-piece trial femoral component kit (16) for use in sizing a femoral cavity prior to implantation of a prosthetic femoral implant, comprising:
 - 30 at least two trial distal components (12', 12'') of different size and dimensions;
 - at least two trial proximal components (14', 14'') of different size and dimensions, said proximal components being repeatably attachable to said distal

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components to form a femoral trial prosthesis having (10) a stem formed by the distal component in combination with a portion of the proximal component, said trial prosthesis and stem thus formed having dimensions with a predetermined relationship to a corresponding femoral implant, wherein each said proximal component has distal and proximal ends and a predetermined length therebetween such that said distal end of the proximal component is positioned within the metaphysis (52) of the femur (40) when the proximal component is seated within the femoral cavity (140).

6. The multi-piece trial component kit (16) of claim 5 wherein the predetermined length of the proximal component is such that said distal end of said proximal component is located between the soft spongy bone of the epiphysis and the hard cortical bone of the metaphysis of the femur when the proximal component is seated within the femoral cavity.

7. The multi-piece trial component kit (16) of claim 5 wherein the predetermined length of the proximal component (14', 14") is such that said distal end (26) of said proximal component is located in the circumferential area between the gluteal tuberosity and about two inches (2") below the pectineal line of the femur when the femoral trial prosthesis is fitted within the femoral cavity.

8. The multi-piece trial component kit (16) of claim 5 wherein the dimensions of the proximal component (14', 14") are smaller than the dimensions of the corresponding prosthetic femoral implant in its proximal region.

9. The multi-piece trial femoral component kit (16) of claim 5 wherein the dimensions of the distal and proximal components are smaller than the dimensions of the corresponding distal and proximal regions of the corresponding prosthetic femoral implant.

10. The multi-piece trial femoral component kit (16) of claim 9 wherein the dimensions of the distal and proximal components are smaller by different amounts than the dimensions of the corresponding regions of the prosthetic femoral implant.

11. The multi-piece femoral kit (16) of claim 9 wherein the diameter of the distal and proximal components are .5 to 1.25 mm smaller than the corresponding diameter of the prosthetic femoral implant.

12. The multi-piece femoral component kit (16) of claim 10 wherein the diameter of the distal component is about .75 mm smaller and the diameter of the

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proximal component is about 1.0 mm smaller than the corresponding diameters of the prosthetic femoral implant.

13. The multi-piece trial component kit (16) of claim 7 wherein the proximal end of the distal component (24) and the distal end of the proximal component (26) together form means (34, 36) for coupling the proximal and distal components together.

14. The multipiece trial component kit (16) of claim 7 further comprising a trial positioner handle (25) repeatably releasably attachable to the distal and proximal components.

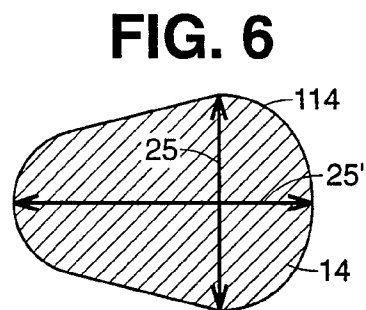
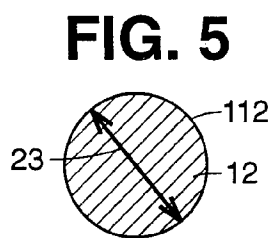
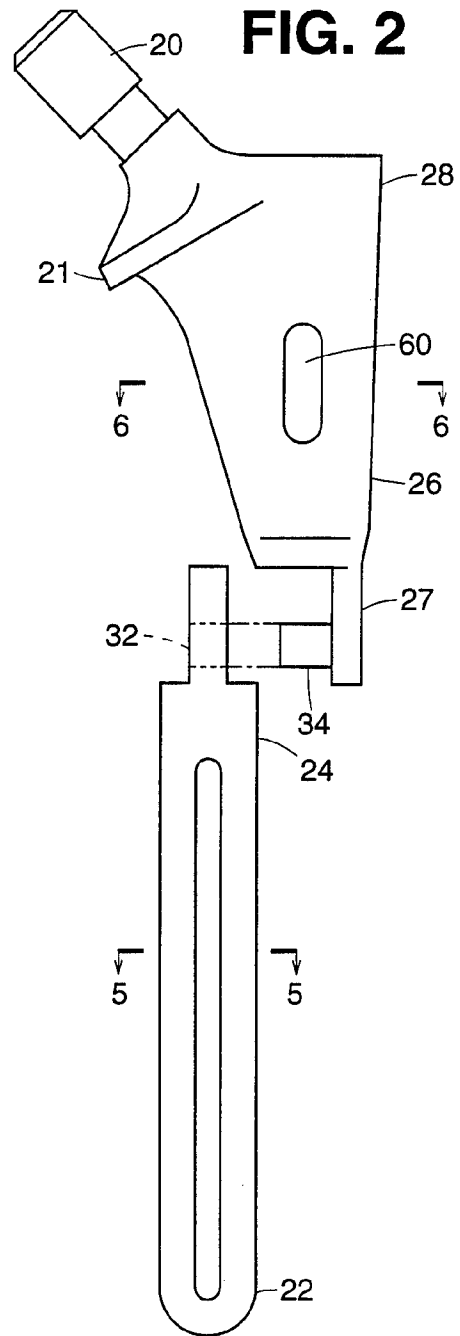
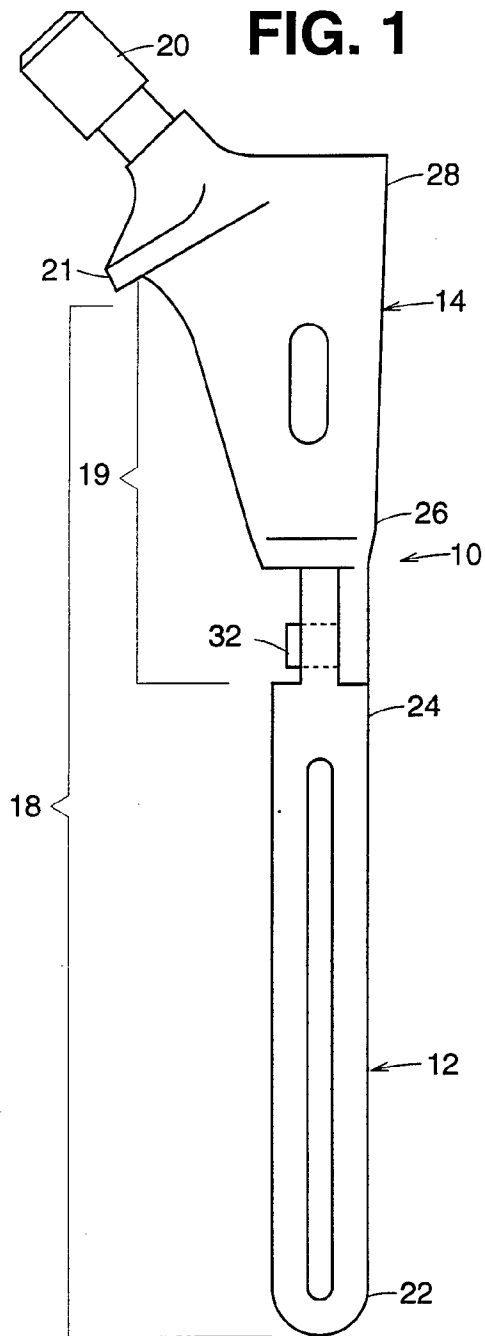
10 15. The multi-piece trial component kit of claim 14 wherein the distal end (134) of the trial positioner handle (25) and the proximal ends of the proximal and distal components together form means for coupling the trial positioner handle and the proximal or distal component together.

16. The multi-piece trial component kit of claim 15 wherein the means for coupling the trial positioner handle (25) to the distal or proximal component is the same as the means (36) for coupling the distal and proximal components together.

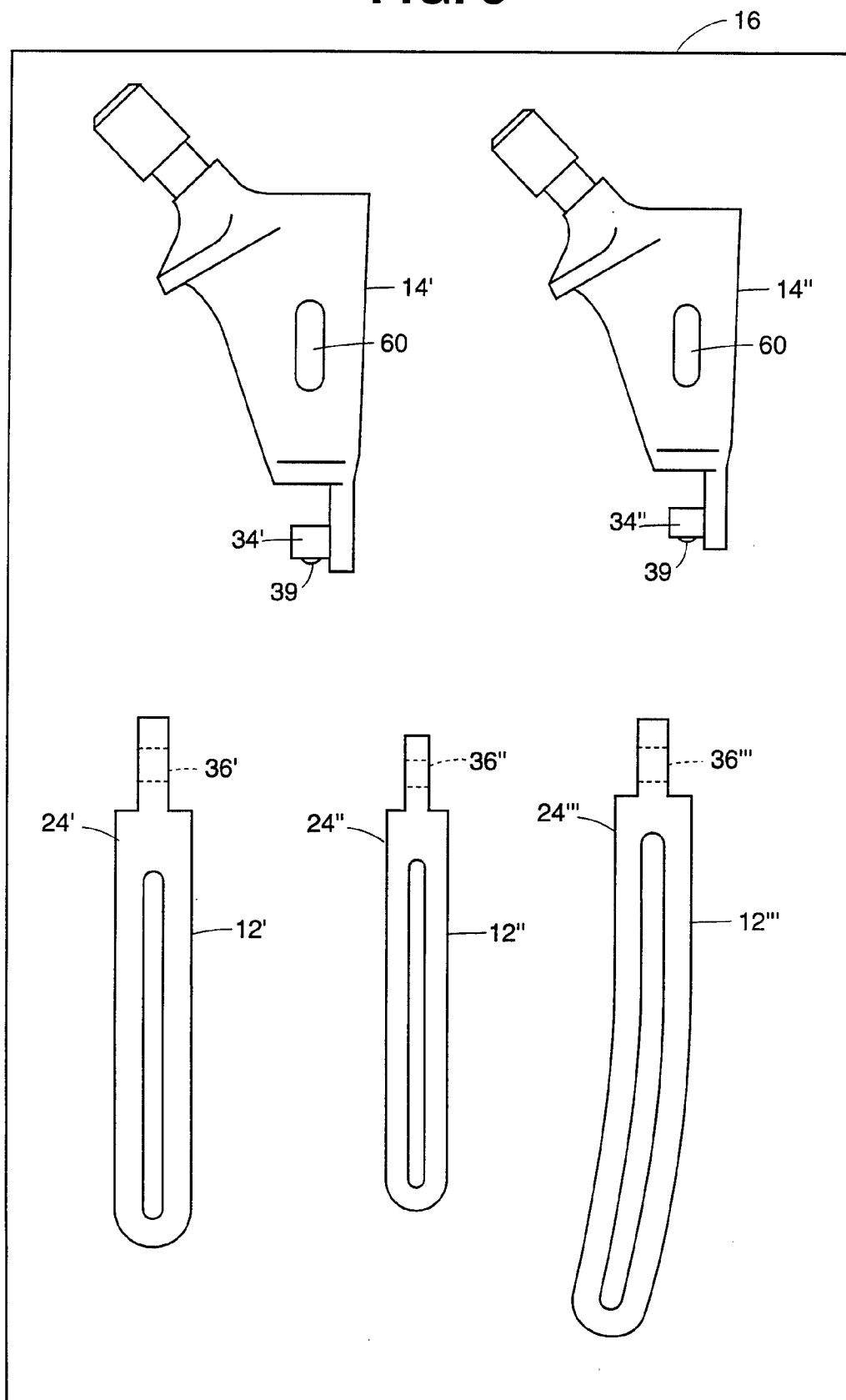
17. The multi-piece trial component kit of claim 15 wherein the means for coupling the trial positioner handle (25) to the proximal component includes an opening (30) formed in the proximal portion of the proximal component.

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2/4

FIG. 3

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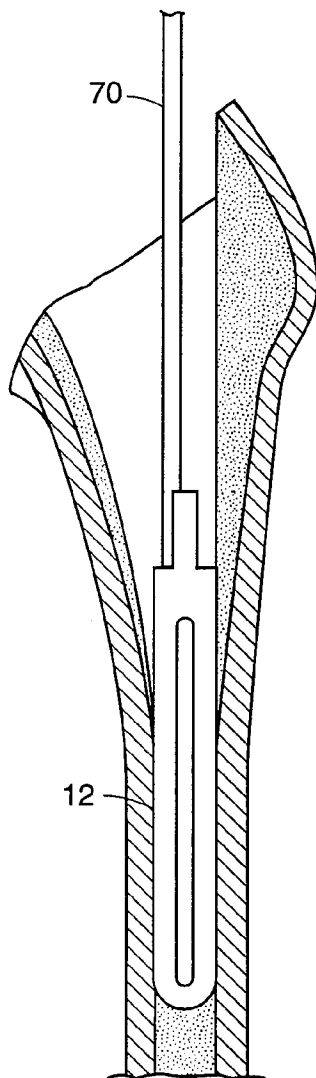


FIG. 8

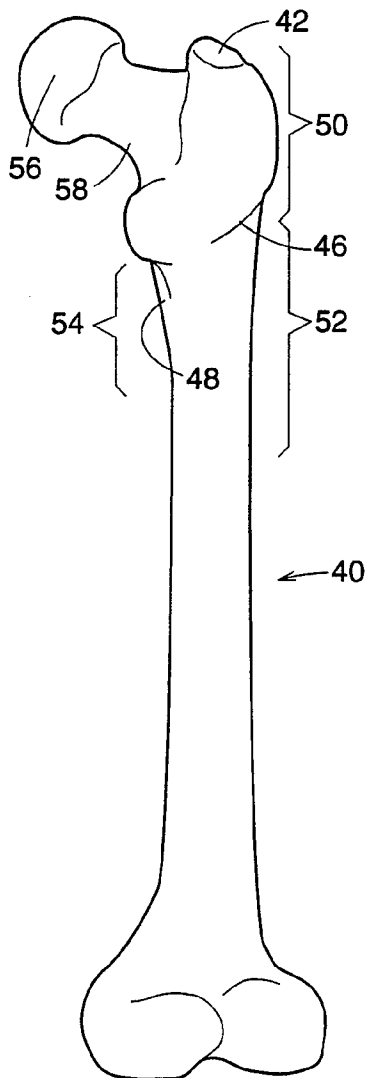


FIG. 4

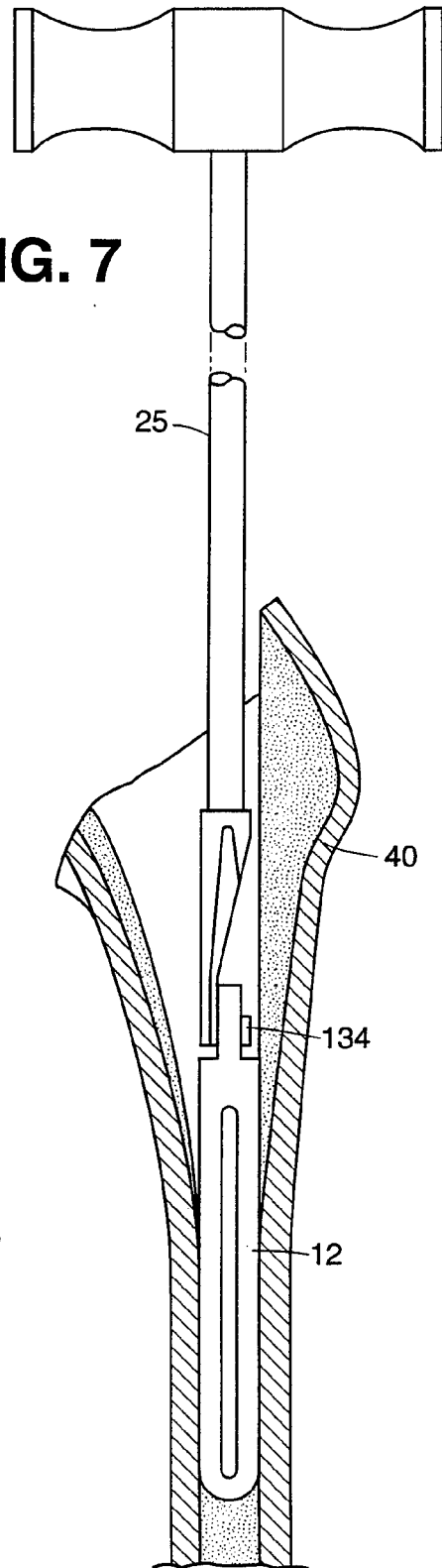
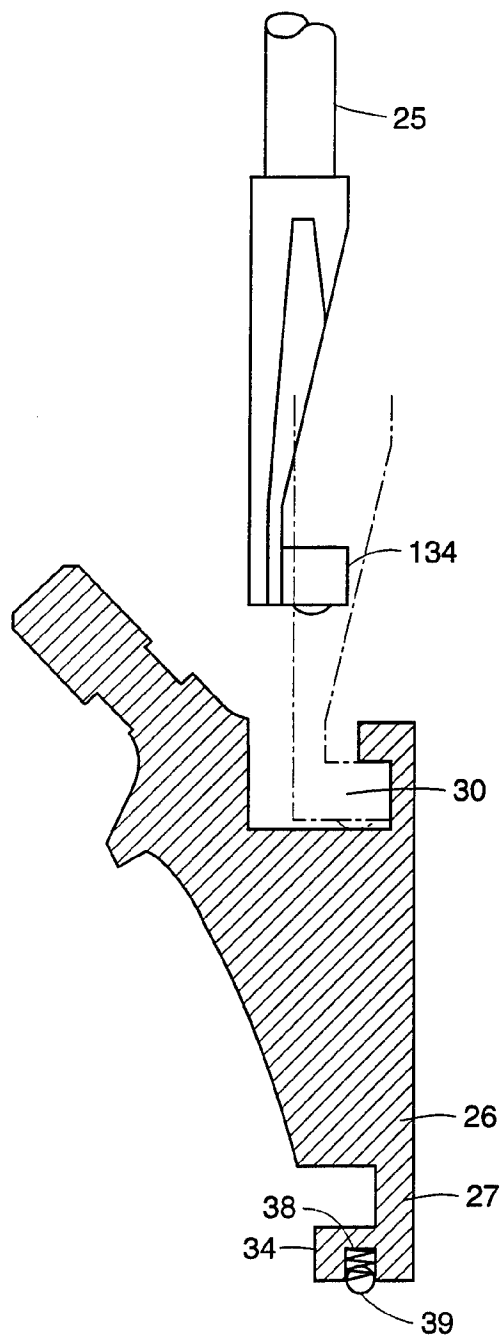
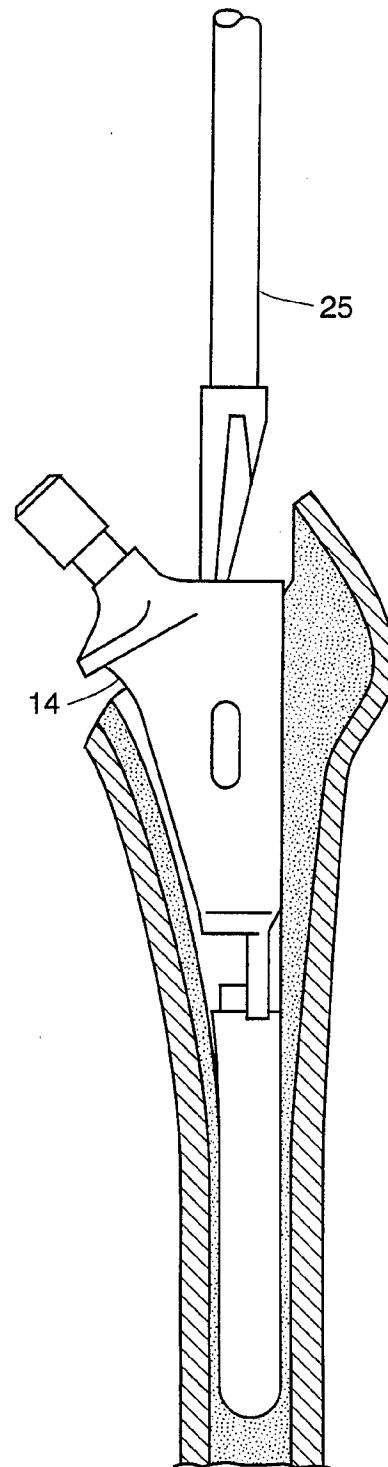


FIG. 7

FIG. 9**FIG. 10**

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 95/00385

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 163 121 (WALDEMAR LINK) 4 December 1985	1-13
Y	see abstract; figures ---	14-17
Y	FR,A,2 660 855 (ORTHOCOGIT) 18 October 1991 see page 6, line 14-23; figures ---	14-17
A	EP,A,0 290 735 (SULZER) 17 November 1988 ---	1,5
A	EP,A,0 359 485 (PFIZER HOSPITAL GROUP) 21 March 1990 ---	1,5
P,X	DE,U,94 18 963 (ARTOS MEDIZINISCH PRODUKTE) 26 January 1995 see the whole document --- -/--	1,5

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

28 July 1995

Date of mailing of the international search report

16.08.95

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US,A,5 342 366 (WHITESIDE) 30 August 1994 see abstract; figure 2 -----	1,5

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 95/00385

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-163121	04-12-85	DE-A- 3417609 DE-A- 3564188 US-A- 4658808	14-11-85 15-09-88 21-04-87
FR-A-2660855	18-10-91	NONE	
EP-A-290735	17-11-88	CH-A- 671689	29-09-89
EP-A-359485	21-03-90	US-A- 5108437 AU-B- 629853 AU-A- 4141089 DE-U- 8911046 JP-A- 2109556	28-04-92 15-10-92 22-03-90 08-02-90 23-04-90
DE-U-9418963	26-01-95	NONE	
US-A-5342366	30-08-94	NONE	